Remarks

Reconsideration and allowance of this application, as amended, are respectfully requested.

Applicants acknowledge with gratitude the personal interview of April 17, 2008, granted by the examiner. During the interview Applicants first summarized the recent prosecution history of the application, i.e., the final Office Action of April 26, 2007 and the Amendment filed August 14, 2007. Applicants reviewed the claim amendments made in the Amendment of August 14 and re-emphasized the arguments that were made in support of patentability.

Then, at the examiner's request, Applicants explained the features of the instant invention. After explaining the details of the device, Applicants emphasized the distinctions between the present invention and the prior art that were made in Applicants' August 14 Amendment. The examiner stated that the combined structural features of Goux and Storey *could* perform the determinations defined in the analysis unit portion of Applicants' claims. The examiner stated that Goux teaches a "control unit and an analysis unit."

In response, Applicants first urged that the previously presented claim language *does* define structural features that distinguish over the prior art. In other words, the language "an analysis unit operatively connected to the at least one sensor and

configured to determine" (claim 1) defines an analysis unit having a *configuration* that enables it to determine blood purification performance L1 and derive blood purification performance L2.

The examiner then asserted that despite the detailed description in the specification of *how* the analysis unit performs the analysis, the claims do not define *structures* that perform the analysis. Applicants then reviewed the specification with the examiner, with particular emphasis on the disclosure at page 16, first paragraph, through page 23, second full paragraph. Applicants then asserted that the claimed analysis unit having the claimed configuration *is* the structure that distinguishes over the applied art, because any person skilled in the art would be intimately familiar with the analysis unit devices such as processors and memory that would be employed by the claimed configuration to "perform," "record," "transmit," "store," and "determine . . . by solving the equation."

Turning to the present Amendment, claims 1-17 remain pending in the application. Claims 1, 14, and 15 are independent. Claims 1-13 have been amended to correct an informality in each. Claims 1, 14, and 15 have been amended to advance prosecution by even more specifically defining the structure of the analysis unit feature. Instant claim 1, for example, defines a blood treatment device that includes, *inter alia*,

> an analysis unit operatively connected to the at least one sensor and configured to determine i) a blood

> purification performance L1 of the blood purification element for the first material based on the measurement values of the at least one sensor and ii) a blood purification performance L2 of the blood purification element for a second material, which is different from the blood purification performance L1 for the first material, based on *data stored in the analysis unit that define a relationship between* the blood purification performance L1 for the first material and *the blood purification performance L2 for the second material.*

Claims 14 and 15 have been amended in a similar manner. Support for the instant recitations of claims 1, 14, and 15 is found at specification page 10, i.e., "on the basis of relationships between the two blood purification performances which are stored in an analysis unit." No new matter has been introduced through the foregoing amendments, and entry of the amendments is respectfully requested. The sole rejection is respectfully submitted to be obviated in view of the amendments and remarks presented herein.

35 U.S.C. § 103(a) - Goux and Storey

Claims 1-17 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over US 5,567,320 to Goux et al. (hereinafter "Goux") in view of US 4,202,760 to Storey et al. ("Storey"). The Office Action asserts that "[i]f the prior art structure is capable of performing the intended use, then it meets the claim" (Office Action page 2). The Office Action also asserts that "Applicant has not provided features of the claimed invention as compared to

features of the prior art, which would render the prior art invention capable of performing the recited functions" (Office Action page 2).

The rejection of claims 1-17 under § 103(a) over Goux and Storey is respectfully deemed to be obviated. The combined disclosures of Goux and Storey would not have rendered obvious Applicants' presently claimed invention. First, contrary to the examiner's assertions, there are structural differences between Applicants' claimed invention and the applied prior art that patentably distinguish the claimed invention from the prior art. Second, there is no teaching whatsoever in either Goux or Storey that would have led one to select the references and combine them in a way that would produce the invention defined by any of Applicants' pending claims.

By way of review and as explained in Applicants' response to the first Office Action filed January 11, 2007, Applicants' invention is based on the following (see instant specification page 10, line 18, through page 11, line 3). Conventional hemodialyzers can determine the blood purification performance of the blood purification element (i.e., the dialysance of the dialyzer) in relation to a first material. For example, the sodium ion dialysance can be determined based on the change in its concentration relative to that in the fresh dialysis fluid.

However, it may also be necessary or desirable to determine the performance of the blood purification element in

relation to a second material. See, e.g., Applicants' disclosure regarding the concentrations of potassium, calcium, and phosphate (specification page 23, line 33, through page 24, line 10).

Thus, an object of Applicants' device is "to determine the second blood purification performance, which is different from the first blood purification performance, for a second material, *without a further measurement method being necessary*" (specification page 10, lines 18-22) (emphasis added). Applicants' device is based on "relationships between the two blood purification performances which are stored in an analysis unit and which go beyond a mere identity assignment for identical blood purification performances as in the case of sodium ions and urea, [so that] the second blood purification performance may be determined directly" (specification page 10, lines 23-29).

Applicants respectfully disagree with the examiner's assertion that "Applicant has not provided features of the claimed invention as compared to features of the prior art, which would render the prior art invention capable of performing the recited functions." Applicants' claims define the features of the invention both structurally and functionally. The *structure* of the analysis unit is the claimed *configuration*. The previously presented claim language of "an analysis unit operatively connected to the at least one sensor and *configured to determine*" (claim 1) defines an analysis unit having a *configuration* (i.e., a structure)

that enables it to determine blood purification performance L1 and derive blood purification performance L2. The asserted combination of Goux and Storey does not teach a device with a configuration that could perform this determination.

Furthermore, contrary to the opinion expressed by the examiner during the interview, it is not necessary that the claim define the specific devices employed in the claimed configuration as long as the analysis unit itself defines over the prior art apparatus. The *structure* of the analysis unit is the claimed *configuration*. Since Goux and Storey do not teach a device with a configuration that could perform the claimed determination, it is not necessary that the claim define devices such as processors and memory that would be employed to perform the "determining" function.

Nonetheless, as indicated above, claims 1, 14, and 15 have been amended to advance prosecution by *even more* specifically defining the structure of the analysis unit feature. Claim 1 defines the analysis unit as being "operatively connected to the at least one sensor and *configured* to determine" blood purification performances L1 and L2. Performance L2 is determined "*based on data stored in the analysis unit that define a relationship* between the blood purification performance L1 for the first material and the blood purification performance L2 for the second material." Thus, instant claim 1 defines an analysis unit having a

configuration that determines the second blood purification performance *without a further measurement method being necessary*. The asserted combination of Goux and Storey simply does not teach a device that could perform this determination.

The combined disclosures of Goux and Storey do not teach all of Applicants' claim features. Neither Goux nor Storey teaches an analysis unit that is configured to determine the blood purification performances L1 and L2 according to Applicants' claimed invention.

The examiner asserts that Goux's "analysis unit 22 is capable of determining the blood purification performance (col. 5, lines 14-59)" (Office Action page 4). The examiner then acknowledges, however, that "Goux does not disclose the device differentiates between two materials . . ." (Office Action page 4).

The examiner is correct in concluding that "Goux does not disclose the device differentiates between two materials . . ." In fact, in the disclosure relied upon by the examiner (specifically, col. 5, lines 24-31), Goux teaches that

> It is by virtue of this correlation that it is possible to calculate the real concentration (Cbin) of blood sodium at the inlet of the exchanger from four measured values of the conductivity of the dialysis fluid (Cd1in, Cd2in, Cd1out, Cd2out, respectively the conductivity at the inlet and the outlet of the exchanger, *measured during the successive passage of a first and of a second dialysis fluid d1, d2 having different conductivities*) . . . (Emphasis added)

Thus, Goux calculates a concentration of blood sodium by measuring conductivity during the successive passage of a first and a second dialysis fluid d1, d2 having different conductivities. But, Goux's device is different from Applicants' claimed invention in that Goux is not configured to differentiate between two materials. As indicated above, an object of Applicants' claimed invention is "to determine the second blood purification performance, which is different from the first blood purification performance, for a second material, *without a further measurement method being necessary.*"

Storey's apparatus is also structurally different from Applicants' claimed device. Storey is directed to an "Apparatus and Method for Preparation of a Hemodialysis Solution Optionally Containing Bicarbonate." The examiner relies upon Storey's disclosure at column 5, lines 1-62. But there, Storey summarizes his invention as follows: "The method of this invention, and the apparatus in loops 50 and 40, provide a spectrum of bicarbonate-acetate containing hemodialysis solutions ranging from no bicarbonate to no acetate" (column 5, lines 34-37). The examiner also relies upon Storey's disclosure at column 1, lines 45-50. There, Storey discloses that "[t]his invention provides a hemodialysis system which enables continuous formulation and supply to an artificial kidney of a hemodialysis solution, or dialysate, which contains the normally present sodium acetate component, or optionally may contain bicarbonate as a partial or total

replacement therefor." Story, therefore, is directed to a sensor *for freshly prepared dialysate*, and fails to disclose Applicants' claimed device that includes, *inter alia*, an analysis unit that is configured *to determine the blood purification performances L1 and L2* as claimed.

And, regardless of what Storey may disclose with regard to the composition of the dialysate (column 5, lines 1-62), the disclosure of Storey does not rectify any of the above-described deficiencies of Goux. Thus, the combined disclosures of Goux and Storey do not teach all of Applicants' claim features.

Furthermore, there is no teaching in either Goux or Storey that would have led one to select the references and combine them in a way that would produce the invention defined by any of Applicants' pending claims. As indicated above, Goux is directed to a device that is able "to calculate the real concentration (Cbin) of blood sodium at the inlet of the exchanger from four measured values of the conductivity of the dialysis fluid." Storey is directed to *preparation* of a hemodialysis solution optionally containing bicarbonate.

That is not Applicants' claimed invention. There is simply no teaching in either Goux or Storey that would have led one to select the references and combine them, let alone in a way that would produce Applicants' claimed invention. In summary, it has simply not been obvious how one would deal with substances having a

different blood purification performance if one has knowledge about the performance of a first substance and would like to derive the (different) blood purification performance of the second substance. Applicants' claimed invention provides the solution. Applicants' claimed device has a structure that not only determines the blood purification performance, but that does so by determining "i) a blood purification performance L1 of the blood purification element for the first material *based on the measurement values of the at least one sensor* and ii) a blood purification performance L2 of the blood purification element for a second material, which is different from the blood purification performance L1 for the first material, *based on data stored in the analysis unit that define a relationship between the blood purification performance L1 for the first material and the blood purification performance L2 for the second material.*" Claims 14 and 15 are similarly allowable.

In view of the foregoing, this application is now in condition for allowance. If the examiner believes that another

interview might expedite prosecution, the examiner is invited to contact the undersigned.

Respectfully submitted,

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